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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,245	02/12/2004	Thomas Antonsson	3764-153	4185

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,245	ANTONSSON ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38,47-49 and 52-65* is/are pending in the application.

4a) Of the above claim(s) *47-49 and 59-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38 and 52-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/776,231.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/12/04;6/2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-43 and 51 in the response to restriction requirement and the amendment filed June 2, 2006 is acknowledged. In the amendment, claims 1-38 and 47 have been amended, claims 39-46 and 50-51 have been cancelled, and new claims 52-65 have been added, thus, claims 1-38, 47-49 and 52-65 are pending. The traversal is on the ground(s) that the claims of Groups I and III are classified in class 514, subclass 18 at least, thus the search can be made without additional burden on the Examiner to examine the subject matter of all the claims that classified in the same class and subclass. Applicants' response has been considered, however, the argument is not found persuasive because of the following reasons. Restriction is proper when two or more claimed inventions are either independent **or** distinct. See MPEP 803. Furthermore, co-examination of the method claims of Group III would have required a search of thrombin-related disorders such as thrombosis and hypercoagulability, and class/subclass 424/9.1. Therefore, co-examination of Group III would require a serious additional burden of search.

The restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the invention is not coextensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the

burden of search. Burden in examining materially different groups having materially different issues also exist. Thus, Group III, claims 47-49 and 59-65 are non-elected inventions and are withdrawn from consideration, and claims 1-38 and 52-58 are examined.

Information Disclosure Statement (IDS)

2. The IDS filed February 12, 2004 and June 2, 2006 are acknowledged. However, some of the references listed in the IDS are crossed out and not considered because they are not found in the parent applications. If applicants wish these references to be considered, please resubmit these references.

Claim Objections

3. Claim 1 is objected to because of misprinted word "C_{1-6} ailcyl" in line 11 and "C_{1-3} alkyiphenyl" in line 16. Since the original claim 1 recites "C_{1-6} alkyl" and "C_{1-3} alkylphenyl" and there is no indication that the words have been changed in the preliminary amendment, thus the words in claim 1 read as "C_{1-6} alkyl" and "C_{1-3} alkylphenyl".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 45 of prior U.S. Patent No. 6,262,028, a double patenting rejection.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v.*

Eagle Mfg. Co., 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-38, 53 and 56-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1-38 are indefinite as to what an effective amount of acetylsalicylic acid and a compound of formula I would do. Claims 2-38 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

7. Claims 10, 11, 14, 17 and 21-23 are indefinite because of the use of the term "may be" or "partially cyclic". The term cited renders the claim indefinite, it is not clear what the term "may be" indicates, e.g., the citation of the latter group "may be" linear, does it mean the latter group is linear, or not linear, or something else? Regarding the term "partially cyclic", it is not clear to what extent the alkyl group is cyclized, e.g., in partially cyclic C_{10} alkyl group, how many carbons are in the cyclic ring (e.g., 4, 5, 6 or 7)?

8. Claim 53, and 56-58 are indefinite because the claim does not define R^1 and R^2 in the formula I, it is not clearwhat structure the compound of formula I has. Claims 56-58 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

9. Claim 57 recites the limitation "separate ...use" in line 2. There is insufficient antecedent basis for this limitation in the claim, because the independent claim, claim 53 recites a combination of components (a) and (b), thus, these two components are suitable for combination use, not in separate use.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-38 and 52-58 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 and 45 of U. S. Patent 6,262,028. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-38 and 52-58 in the instant application disclose a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C$-CH_2-(*R*)Cgl-Aze-Pab-R^2, where R^1 and R^2 are defined; and a combination comprising

acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$. This is obvious variation in view of claims 1-39 and 45 of the patent which disclose a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$; a pharmaceutical formulation including a compound of formula I or a pharmaceutically acceptable salt thereof, in admixture with a pharmaceutical carrier; and a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$; and the specification discloses the compounds of invention may be combined and/or co-administered with an antiplatelet agent such as acetylsalicylic acid (column 11, lines 16-37). Both sets of claims cite a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$; and a combination comprising acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$. Thus, claims 1-38 and 52-58 in present application and claims 1-39 and 45 in the patent are obvious variation of a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$; and a combination comprising acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$.

11. Claims 1, 10-13, 31-35, 37 and 52-58 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U. S. Patent 6,262,028. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 10-13, 31-35, 37 and 52-58 in the instant application disclose a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$, where R^1 can be H or $C_{1\text{-}10}$ alkyl,

and R^2 can be OH; and a combination comprising acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$. This is obvious variation in view of claims 1-14 of the patent which disclose a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$, where R^1 is H or $C_{1\text{-}10}$ alkyl, and R^2 is OH; and a pharmaceutical formulation including a compound of formula I or a pharmaceutically acceptable salt thereof, in admixture with a pharmaceutical carrier; and the specification discloses the compounds of invention may be combined and/or co-administered with an antiplatelet agent such as acetylsalicylic acid, and an effective doses (i.e., 0.001-100 mg/kg body weight) of the compound of formulation I can be used in the treatment (column 10, lines 42-65). Both sets of claims cite a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$, where R^1 is H or $C_{1\text{-}10}$ alkyl, and R^2 is OH; and a combination comprising acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$ in the formulation. Thus, claims 1, 10-13, 31-35, 37 and 52-58 in present application and claims 1-14 in the patent are obvious variation of a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$, where R^1 is H or $C_{1\text{-}10}$ alkyl, and R^2 is OH; and a combination comprising acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$ in the formulation.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
July 21, 2006